REMARKS

Claims 1, 3, 5-7, 9-19, 22 and 23 are pending in the application. Claims 16-18 were previously withdrawn from consideration and claims 4 and 8 were previously canceled. Claims 1, 3, 5-7, 9-15, 19 and 21 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 3,605,123 (Hahn). Claims 1 and 15 have been amended, new claims 22 and 23 have been added and claim 7 has been canceled by way of the present amendment. Reconsideration is respectfully requested.

103 Claim Rejections

Claims 1-3, 5-7, 9-15, 19 and 21 were rejected under 35 U.S.C. Section 103(a) as unpatentable by Hahn. Applicants respectfully traverse the rejection.

Claims 19 and 21 have been canceled by way of the present amendment. Claims 1 and 15 have been amended to clarify the invention. In particular, claim 1 has been amended to recite:

> a channel network (6) that gives the layer porosity,
> ~~wherein the layer is established on an undulating or uneven surface present on the implant and having has a roughness value in the range of 0.4 - 5 μm, for the purpose of increasing a total volume of the layer to a range between 5 X 10^{-2} and 10^{-5} cm^3,~~
> wherein the channel network (6) has mouths (3', 4') on a surface (2a') of the layer (2''') adjacent to the bone or tissue structure and whose respective cross-sectional diameters (D) are in the range of 0.1~~μμm~~ to 10 μm at the surface (2a') of the layer,
> wherein different sizes for the cross-sectional diameters of the mouth ~~are given different sizes to~~ create conditions for bone growth ~~with a predefined penetration function~~,
> wherein the mouths of the channel network have cross-sectional diameters that are less than the respective depths of the channels in and down into the layer as seen from said surface (2a'),
> wherein the diameters of the mouths and the depths of the channels stimulate bone growth ~~by means of diffusion~~ and contribute to the incorporation of the implant in the bone or tissue structure, ~~and~~
> wherein the channel network (6) comprises a combination of contiguous channel branches (12, 13, 14, 15, 16) which extend in at least both vertical and lateral directions within the layer (2''')

and toward a transition (11) between the layer (2''') and the implant (1''), and

wherein the layer has an average thickness in the range of 0.5 – 20 μm and the layer is an oxide layer.

Claim 15 has been amended with similar language. Support for the amendments is provided by the original specification, claims and figures. Therefore, the amendments raise no questions of new matter.

Hahn discloses a permanent implant for bone tissue which has a dense cast or wrought base portion of high strength metal, and a porous metal layer overlying and bonded to the base portion.[1] In particular, Hahn discloses a prosthesis **10** that includes a pin or shaft **11** and ball **12**.[2] In addition, Hahn discloses the prosthesis **10** may be composed of metals such as titanium.[3]

Further, Hahn discloses the titanium prosthesis **10** is coated, on the pin or shaft **11**, with a relatively thick porous layer of titanium **13**.[4] In particular, Hahn discloses, that at the interface between the shaft **11** and layer **13** is, for practical purposes *free of pores or interstices* (emphasis added).[5] Further, Hahn discloses that the pores will range from about *30 microns to about 200 microns* wide at the opening or mouth (emphasis added).[6] Further, Hahn discloses that the coating thickness is approximately 0.1 inch and the preferred thickness is from about *0.015 to about 0.030 inches*.[7]

Furthermore, Hahn discloses a process for providing a high strength bond between the coating **13** and base metal shaft **11** using a plasma flame. In particular, Hahn discloses *no* porosity or practically no porosity exists at the interface between the coating **13** and surface of the base metal shaft **11** and gradually increasing porosity, along with pore size and pore density, in moving away from the interface between the surface of the base metal and the coating **13**.

However, it is respectfully submitted that Hahn nowhere discloses, as amended claim 1 recites:

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[1] Hahn at Abstract.
[2] *Id.* at column 3, lines 30-33.
[3] *Id.* at column 3, lines 33-35.
[4] *Id.* at column 3, lines 43-45.
[5] *Id.* at column 3, lines 55-58.
[6] Id. at column 3, lines 63-66.
[7] *Id.* at column 3, lines 47-54.

a channel network (6) that gives the layer porosity,
wherein the channel network (6) has *mouths (3', 4'), channels and channel branches on a surface (2a') of the layer (2''') adjacent to the bone or tissue structure and whose respective cross-sectional diameters (D) are in the range of 0.1μm to 10 μm* at the surface (2a') of the layer,
wherein different sizes for the cross-sectional diameters of the mouths create conditions for bone growth,
wherein the mouths of the channel network have cross-sectional diameters that are less than the respective depths of the channels in and down into the layer as seen from said surface (2a'),
wherein the diameters of the mouths and the depths of the channels stimulate bone growth and contribute to the incorporation of the implant in the bone or tissue structure,
wherein the channel network (6) comprises a combination of contiguous channel branches (12, 13, 14, 15, 16) which extend in at least both vertical and lateral directions within the layer (2''') and toward a transition (11) between the layer (2''') and the implant (1''), and
wherein the layer has an average thickness in the range of 0.5 – 20 μm and the layer is an oxide layer (emphasis added).

Independent claim 15 has been similarly amended. That is, Hahn nowhere discloses that "different sizes for the cross-sectional diameters of the mouths create conditions for bone growth" or that "the layer has an average thickness in the range of 0.5 – 20 μm and the layer is an oxidized layer." In addition, in contrast to the conventional plasma spraying technique of coating disclosed by Hahn, the present invention accomplishes coating by use of an anodic oxidation method.

Further, it is respectfully submitted that, with respect to Hahn and the claimed invention there are differences: (1) in the technique for applying the coating (i.e., Hahn discloses the titanium member **10** is coated, on the pin or shaft **11**, with a relatively thick porous layer of titanium **13**[8]; and (2) in the size and magnitude of the diameter of the mouths and coating thickness (i.e., Hahn discloses that the pores will range from about 30 microns to about 200

[8] *Id.* at column 3, lines 43-45.

microns wide at the opening or mouths[9] and coating thickness is approximately 0.1 inch and the preferred thickness is from about 0.015 to about 0.030 inches[10]).

In particular, the coating of item (1) is applied with a plasma spray technique. It is respectfully submitted that coating with an oxidized layer provides different results, in terms of porosity, as compared to the plasma spray technique of Hahn. That is, the plasma spraying technique of Hahn will *not* form the recited: "channel network" that gives the recited "layer" porosity.

Moreover, with regards to item (2) the "layer" of the claimed invention: "has an average thickness in the range of 0.5 – 20 μm." This in contrast to the coating thickness of 30 microns to about 200 microns, as discussed above for Hahn.

Furthermore, in contrast to Hahn, as discussed in item (1) and item (2) above, the claimed invention recites: "mouths (3', 4') on a surface (2a') of the layer (2''') adjacent to the bone or tissue structure and whose respective cross-sectional diameters (D) are in the range of 0.1μm to 10 μm"; and "the layer has an average thickness in the range of 0.5 – 20 μm and the layer is *an oxidized layer* (emphasis added)."

Thus, in consideration of the above discussion, it is respectfully submitted that Hahn does not disclose and actually teaches away from the claimed invention. Therefore, it is respectfully submitted that Hahn does not disclose, suggest or make obvious the limitations of claims 1-3, 5-7 and 9-15. Therefore, it is respectfully submitted that independent claims 1 and 15, and claims dependent thereon, patentably distinguish over Hahn.

New Claims

New claims 22 and 23 have been added by way of the present amendment to claim additional features of the invention. In particular, new claims 22 and 23 recite:

[9] Id. at column 3, lines 63-66.
[10] *Id.* at column 3, lines 47-54.

wherein the implant has a surface further comprising mouths, channels and channel branches having diameters in a range of 0.1 μm to 1.5 μm and that comprise 20% of the surface.

Support for the new claims is provided at least at page 12, lines 11 to 22, and as shown at least in **FIG. 4** of originally filed specification. Therefore, the new claims raise no questions of new matter.

New claims 22 and 23 are dependent upon independent claims 1 and 15, respectively. Thus, at least for the same reasons discussed above for claims 1 and 15, new claims 22 and 23 patentably distinguish over Hahn. In addition, it is respectfully submitted that Hahn nowhere discloses the limitations recited above in new claims 22 and 23. Therefore, it is respectfully submitted that Hahn does not disclose, suggest or make obvious the limitations of new claims 22 and 23 and that these new claims patentably distinguish thereover.

Conclusion

In view of the above amendments and remarks, reconsideration and allowance of the pending claims are respectfully requested. Applicants believe that the present application is in condition for allowance, and an early indication of the same is respectfully requested. In the event the Examiner believes an interview might serve to advance the prosecution of this application in any way, the undersigned is available at the telephone number noted below.

The Director is hereby authorized to charge any fees, or credit any overpayment, associated with this communication, including any extension fees, to Deposit Account No. 22-0185 under docket number 21547-00283.

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Respectfully submitted,

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